

3-1-2018

## **Factors associated with health-related quality of life, hip function, and health utility after operative management of femoral neck fractures**

S. Sprague  
*McMaster University, Faculty of Health Sciences*

M. Bhandari  
*McMaster University, Faculty of Health Sciences*

M. J. Heetveld

S. Liew  
*Monash University*

T. Scott  
*McMaster University*

*See next page for additional authors*

Follow this and additional works at: <https://ir.lib.uwo.ca/boneandjointpub>



Part of the [Medicine and Health Sciences Commons](#)

---

### **Citation of this paper:**

Sprague, S.; Bhandari, M.; Heetveld, M. J.; Liew, S.; Scott, T.; Bzovsky, S.; Heels-Ansdell, D.; Zhou, Q.; Swiontkowski, M.; and Schemitsch, E. H., "Factors associated with health-related quality of life, hip function, and health utility after operative management of femoral neck fractures" (2018). *Bone and Joint Institute*. 1108.

<https://ir.lib.uwo.ca/boneandjointpub/1108>

---

## Authors

S. Sprague, M. Bhandari, M. J. Heetveld, S. Liew, T. Scott, S. Bzovsky, D. Heels-Ansdell, Q. Zhou, M. Swiontkowski, and E. H. Schemitsch

# **Factors associated with health-related quality of life, hip function, and health utility after operative management of femoral neck fractures**

S. Sprague, M. Bhandari, M. J. Heetveld, S. Liew, T. Scott, S. Bzovsky, D. Heels-Ansdell, Q. Zhou, M. Swiontkowski, E. H. Schemitsch

On behalf of the FAITH Investigators (see supplementary material for a full list)

## **Abstract**

### **Aims**

The primary aim of this prognostic study was to identify baseline factors associated with physical health-related quality of life (HRQL) in patients after a femoral neck fracture. The secondary aims were to identify baseline factors associated with mental HRQL, hip function, and health utility.

### **Patients and Methods**

Patients who were enrolled in the Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH) trial completed the 12-item Short Form Health Survey (SF-12), Western Ontario and McMaster Universities Arthritis Index, and EuroQol 5-Dimension at regular intervals for 24 months. We conducted multilevel mixed models to identify factors potentially associated with HRQL.

### **Results**

The following were associated with lower physical HRQL: older age (-1.42 for every ten-year increase, 95% confidence interval (CI) -2.17 to -0.67,  $p < 0.001$ ); female gender (-1.52, 95% CI -3.00 to -0.05,  $p = 0.04$ ); higher body mass index (-0.69 for every five-point increase, 95% CI -1.36 to -0.02,  $p = 0.04$ ); American Society of Anesthesiologists class III (versus class I) (-3.19, 95% CI -5.73 to -0.66,  $p = 0.01$ ); and sustaining a displaced fracture (-2.18, 95% CI -3.88 to -0.49,  $p = 0.01$ ). Additional factors were associated with mental HRQL, hip function, and health utility.

### **Conclusion**

We identified several baseline factors associated with lower HRQL, hip function, and utility after a femoral neck fracture. These findings may be used by clinicians to inform treatment and outcomes.

## **Introduction**

Intracapsular fractures of the femoral neck (basal, mid-cervical, and subcapital fracture lines) are common and account for approximately 50% of all fractures involving the hip.<sup>1</sup> Internal fixation is the preferred treatment for patients with an undisplaced fracture and may also be used to treat those with a displaced fracture, depending on the characteristics of the patient and the preference of the surgeon.<sup>2,3</sup> While fixation preserves the hip joint, patients treated in this way are at risk of complications such as avascular necrosis, nonunion, implant failure, infection, and shortening at the site of the fracture.<sup>4-6</sup> These complications may require additional surgery and result in diminished health-related quality of life (HRQL) and function.<sup>4,7-9</sup> Previous studies have examined factors associated with HRQL and function after a fracture of the hip,<sup>9-12</sup> with two studies looking at this specifically in elderly patients who have sustained a femoral neck fracture treated by fixation.<sup>13,14</sup> These studies reported that HRQL and health utility, as measured by the

EuroQol (EQ)-5D,<sup>15</sup> were significantly lower in those who suffered a complication, those with comorbidities affecting rehabilitation, and those with a displaced fracture. However, both studies were conducted using the same cohort of patients, which included only 90 patients and consequently could not examine all relevant factors. Identifying additional factors associated with reductions in HRQL, function, and health utility may help to optimize the care of these patients.

The recently completed Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH) trial was a multicentre, randomized controlled trial comparing two methods of fixation, cancellous screws versus sliding hip screw (SHS) in patients with a femoral neck fracture.<sup>4</sup> Using data from this trial, our aim in this prognostic study was to determine which baseline factors are associated with HRQL, the function of the hip, and health utility in patients after a femoral neck fracture treated with fixation.

### **Patients and Methods**

The FAITH trial. Patients aged > 50 years with a low-energy femoral neck fracture (basal, mid-cervical, or subcapital fracture lines) were eligible for inclusion in the FAITH trial. The protocol and results have been published.<sup>4,16</sup> The trial was approved by the ethics board of McMaster University (REB# 06-402) and by the ethics board at each participating clinical site. The study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier: NCT00761813).

Health-related quality of life. The FAITH trial included HRQL, hip function, and health utility as secondary outcomes for a subset of patients collected between March 2008 and March 2014. HRQL was measured using the 12-item Short Form Health Survey (SF-12), which involves an eight-domain profile of function and wellbeing and physical and mental health summary measures.<sup>17</sup> Each domain was scored separately from 0 (lowest) to 100 (highest) using standardized methods to calculate a physical and mental component score (PCS and MCS). The minimally important difference (MID) for the SF-12 is five.<sup>17</sup> Hip function was measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire,<sup>18</sup> which includes 24 items to assess pain, stiffness, and function in patients with osteoarthritis of the hip or knee. Scores range from 0 to 100, with higher scores indicating worse pain, stiffness, and limitations of function. Previous research has reported a MID for global WOMAC score of 1.29 for worsening and 0.67 for improvement.<sup>19</sup> Health utility was measured using the EQ-5D questionnaire,<sup>15</sup> which is a standardized five-item instrument measuring health status. Scores range from 0 to 1, with lower scores indicating worse utility. Previous research has reported a MID of 0.074 for the EQ-5D.<sup>20</sup> All questionnaires were administered by research personnel at baseline, recording the recollection of the prefracture status, and at one week, ten weeks, and six, nine, 12, 18, and 24 months postoperatively.

Selection of baseline factors. We selected baseline factors a priori based on biological rationale and previous reports in the literature. Specifically, a systematic review of studies investigating HRQL and health status following fractures of the hip found that the mental state, prefracture functioning on physical and psychosocial domains, comorbidity, female gender, nutritional status, postoperative pain, length of stay in hospital, and complications were factors associated with HRQL or health status.<sup>9</sup> Another study reported associations between health utility and pain, mobility, independence in activities of daily living, and independent living situation for patients with a fracture of the hip treated by fixation.<sup>13</sup> Finally, one study reported an association between the displacement of the fracture and health utility in patients with a fracture of the hip treated by fixation.<sup>14</sup> Based on these findings and data collected in the FAITH trial,

we selected the following additional variables for inclusion in our model: baseline HRQL, hip function, health utility scores, prefracture living setting and functional status, American Society of Anesthesiologists (ASA) classification,<sup>21</sup> body mass index (BMI), diabetic status, and gender. Additionally, we included an interaction term between randomized treatment (cancellous screws or SHS) and smoking status. We included this term because the FAITH trial found three subgroup variables that were significant for the primary outcome of revision surgery within 24 months (displacement, the level of the fracture line, and smoking status). However, when all three were entered into a single model, only smoking status remained significant.<sup>4</sup> The quality of reduction was not included in the models as a surgical characteristic, as less than 0.5% of patients in the FAITH trial were deemed to have an unacceptable quality of reduction by the Central Adjudication Committee.<sup>4</sup> Finally, all models were adjusted for respective baseline HRQL, hip function, and health utility scores. For each potential factor, we proposed a priori a hypothesized effect for all four dependent variables (i.e. SF-12 PCS, SF-12 MCS, WOMAC score, and EQ-5D score). In order to avoid an overfitted or unstable model, there should be at least ten times the number of observations as there are factors in a linear regression multilevel mixed model.<sup>22</sup> Given that there were at least 563 patients in each model, up to 56 factors could be included without overfitting. We classified all baseline factors into one of three groups (characteristics of the patients, of the fracture, or of the operation).

**Definition of baseline factors.** Characteristics of the patients: We analyzed age and BMI as continuous variables. We analyzed all other baseline characteristic variables categorically (i.e. gender (male vs female), ASA classification (i.e. class I vs class II vs class III vs class IV vs class V), prefracture living setting (i.e. institutionalized vs not institutionalized), prefracture functional status (using walking aids vs walking independently), smoking status (current smoker vs not current smoker), and diabetic status (diabetic vs not diabetic)).

**Characteristics of the fracture:** We analyzed all the variables categorically (i.e. displacement (undisplaced vs displaced), level of the fracture (i.e. subcapital vs midcervical vs basal), and Pauwels classification (type I vs type II vs type III)).<sup>23,24</sup>

**Characteristics of the operation:** We analyzed time from injury to surgery as a continuous variable. All other variables were analyzed categorically (i.e. type of reduction (none vs closed vs open), quality of placement of the fixation device (acceptable vs unacceptable) and randomized treatment group (cancellous screws vs SHS)).

**Statistical analysis.** Our statistical analysis plan was determined a priori. We included FAITH trial patients with complete data for all factors and respective baseline HRQL, hip function, and health utility measures in each model. Those who withdrew early from the trial (e.g. due to death or loss to follow-up) were included in the analysis as long as complete data were available for all variables. We used descriptive statistics to summarize all factors (frequencies and percentages for categorical variables, and means and ranges for continuous variables). Before entering the factors into the multivariable models, we calculated all pairwise correlations or associations between variables. We calculated correlations between continuous variables using Pearson's correlation coefficient, and between categorical variables using Cramer's V statistics. For comparison between continuous and categorical variables, we calculated point-biserial correlation (for a binary variable) or the R-squared of the analysis of variance for categorical variables with three or more categories. We decided a priori that if any variables were highly correlated (i.e. 0.7 or higher), only one variable would be included in the model.

We conducted four multilevel, repeated-measures mixed models with three levels (centre, participant, and time), with patient and centre entered as random effects. Multilevel analyses

were selected to account for clustering within centres and patients across several timepoints. We used SF-12 PCS, SF-12 MCS, EQ-5D, and WOMAC scores as the dependent variables (one for each model). We included all factors specified above as independent variables in fixed effects as well as time of HRQL or function assessment (six, 12, and 24 months postoperatively). We included preinjury SF-12 PCS, SF-12 MCS, EQ-5D, and WOMAC scores as an adjustment variable in the respective models.

We decided a priori that the SF-12 PCS would be the primary analysis and other questionnaires would be secondary (SF-12 MCS, EQ-5D, and WOMAC). We anticipated that the results would be similar across the SF-12 PCS, EQ-5D, and WOMAC analyses as they measure similar attributes. Overall, we considered factors that remained conserved across the models as being more plausible, and those which were inconsistently associated to be less plausible. All tests were two-tailed with  $\alpha = 0.05$ . A p-value  $< 0.05$  was considered statistically significant. We used SAS software, version 9.4 (SAS Institute, Cary, North Carolina) for the statistical analyses.

## Results

### Baseline characteristics

A total of 627 patients with a femoral neck fracture met the inclusion criteria for at least one model in the analysis. Their mean age was 72.5 years (62.4 to 99.0); most (397, 63.3%) were women, were not institutionalized (612, 97.6%), were not current smokers (515, 82.1%), were not diabetic (529, 84.4%), had an undisplaced fracture (447, 71.3%), and were treated by closed reduction and internal fixation (386, 61.6%) (Table I).

### Factors associated with postfracture SF-12 PCS

A total of 563 patients (89.8%) met the inclusion criteria for the SF-12 PCS model. We found that the following factors were associated with significantly lower mean postfracture SF-12 PCS (indicating worse HRQL): higher age (-1.42 for every ten-year increase, 95% confidence interval (CI) -2.17 to -0.67,  $p < 0.001$ ), female gender (-1.52 vs male, 95% CI -3.00 to -0.05,  $p = 0.04$ ), higher BMI (-0.69 for every five-point increase, 95% CI -1.36 to -0.02,  $p = 0.04$ ), ASA class III (-3.19 vs class I, 95% CI -5.73 to -0.66,  $p = 0.01$ ), and displaced fracture (-2.18 compared with undisplaced, 95% CI -3.88 to -0.49,  $p = 0.01$ ) (Table II). Additionally, smokers treated by internal fixation using a SHS had a significantly higher postfracture SF-12 PCS than those treated with cancellous screws (3.35, 95% CI 0.02 to 6.67,  $p = 0.048$ ). In former or non-smokers, there was no difference in postfracture SF-12 PCS between those treated with cancellous screws and those treated with a SHS. None of the statistically significant adjusted mean differences reached the MID for the SF-12 PCS. No other factors were found to be significantly associated with postfracture SF-12 PCS.

### Factors associated with postfracture SF-12 MCS

A total of 563 patients (89.8%) also met the inclusion criteria for the SF-12 MCS model. We found the following factors were associated with a significantly lower mean postfracture SF-12 MCS (indicating worse HRQL): female gender (-2.10 vs male, 95% CI -3.50 to -0.71,  $p = 0.03$ ), ASA class III (-3.17 vs class I, 95% CI -5.49 to -0.84,  $p = 0.01$ ), and displaced fracture (-1.80 vs undisplaced, 95% CI -3.39 to -0.21,  $p = 0.02$ ) (Table III). None of the statistically significant adjusted mean differences reached the MID for the SF-12 MCS. No other factors were found to be significantly associated with postfracture SF-12 MCS.

#### Factors associated with post-fracture WOMAC score

A total of 604 patients (96.3%) met the inclusion criteria for the WOMAC model. We found that a displaced fracture (compared with undisplaced) was associated with a significantly higher mean postfracture WOMAC score, indicating worse function (3.77, 95% CI 0.73 to 6.81,  $p = 0.02$ ) (Table IV). This difference was clinically significant. No other factors were found to be significantly associated with the WOMAC score.

#### Factors associated with EQ-5D score

A total of 581 patients (92.6%) met the inclusion criteria for the EQ-5D model. We found that the following factors were associated with significantly lower mean postfracture EQ-5D scores, indicating worse health utility: higher age (-0.01 for every ten-year increase, 95% CI -0.02 to -0.002,  $p = 0.02$ ), female gender (-0.04 vs male, 95% CI -0.06 to -0.02,  $p < 0.001$ ), higher BMI (-0.02 for every five-point increase, 95% CI -0.03 to -0.01,  $p < 0.001$ ), ASA class II (-0.03 vs class I, 95% CI -0.05 to -0.001,  $p = 0.04$ ), ASA class III (-0.07 vs class I, 95% CI -0.11 to -0.04,  $p < 0.001$ ), ASA class IV (-0.10 vs class I, 95% CI -0.17 to -0.04,  $p = 0.002$ ), a displaced fracture (-0.05 vs undisplaced, 95% CI -0.07 to -0.03,  $p < 0.001$ ), and closed reduction (-0.03 vs no reduction, 95% CI -0.05 to -0.01,  $p = 0.01$ ) (Table V). Only the adjusted mean differences for ASA class III and IV, compared with class I were clinically significant. No other factors were found to be significantly associated with EQ-5D scores.

## Discussion

We found that sustaining a displaced femoral neck fracture, compared with an undisplaced fracture, was significantly associated with lower postfracture HRQL, hip function, and health utility scores across all four measures. Additionally, we found that female gender and ASA class III (compared with class I) were significantly associated with lower postfracture SF-12 PCS, SF-12 MCS, and EQ-5D scores, and that older age and higher BMI were significantly associated with lower postfracture SF-12 PCS and EQ-5D scores. Finally, we found that ASA class II and IV (compared with class I) and closed reduction (compared with no reduction) were significantly associated with lower postfracture EQ-5D scores.

These findings must be interpreted with caution as only the association between a displaced fracture and higher WOMAC scores was clinically significant. Tidermark et al<sup>14</sup> also reported an association between a displaced femoral neck fracture and lower postfracture HRQL in a prospective study. In a study including 90 elderly patients with a fracture of the femoral neck, they found that HRQL, as measured by the EQ-5D, was significantly lower in those with a displaced fracture that healed uneventfully compared with those with an undisplaced fracture that healed uneventfully, 26 months postoperatively. This difference surpassed the MID reported for the EQ-5D.<sup>20</sup> However, a smaller prospective study of 45 patients, including 24 with a femoral neck fracture and 21 with a trochanteric fracture, reported no significant differences in HRQL, as measured by the 36-item Short Form Health Survey (SF-36), between those with displaced and undisplaced fractures, four months postfracture.<sup>25</sup> This discrepancy may be explained by the small sample size, short follow-up, and inclusion of patients with trochanteric fractures in the latter study.<sup>25</sup> To the best of our knowledge, no studies to date have looked at the association between gender or ASA classification and HRQL, hip function, and health utility specifically in

patients who have sustained a femoral neck fracture. However, a systematic review examining factors associated with HRQL in many types of hip fractures concluded that there was strong evidence that female gender was associated with lower HRQL scores.<sup>9</sup> ASA class was not included as an outcome in this review. However, the authors reported strong evidence that comorbidity was negatively associated with HRQL which may relate to ASA classification as comorbidities can increase the ASA class.<sup>26</sup>

The importance of including patient specific outcomes, such as HRQL, hip function, and health utility, in clinical trials is being increasingly recognized.<sup>27</sup> However, when looking at these outcomes, it is important to assess whether statistically significant results are also clinically significant.<sup>28</sup> While a number of statistically significant predictors of HRQL, function, and health utility were identified in our study, few were clinically significant. Specifically, only the adjusted mean difference for a displaced fracture in the WOMAC model, and ASA class III and IV (compared with class I) in the EQ-5D model, were found to be clinically significant. Our findings show that while a number of factors may be associated with small changes in HRQL, function and health utility, few are associated with any meaningful differences in these outcomes for patients. This may suggest a need for clinicians and researchers to explore adjuvant therapies or psychosocial interventions, to help improve the HRQL, function, and health utility of patients following a femoral neck fracture.

This study has several methodological strengths. To the best of our knowledge, it is the first to focus on several factors associated with HRQL, hip function, and health utility in a large prospective cohort of patients with a femoral neck fracture. The large sample size and prospective collection of data contribute to the validity of the results, as does the inclusion of four different outcome measures. Additionally, data were collected from 65 centres in five countries (Canada, The United States, The Netherlands, Norway, and Australia), which increases the applicability of the findings. The study is also strengthened by the 24-month follow-up period, which allows a long-term assessment of the patients, as well as the multilevel mixed model analysis, which accounts for changes in HRQL, hip function, and health utility over time and minimizes the impact of confounding variables. Despite these strengths, the study is limited in the context of its design. Due to the use of a nonrandomized design, it is only possible to conclude that an association exists between factors and HRQL, hip function, and health utility, but not the causation of these relationships. Therefore, recommendations based on these results must be interpreted within the context of the design of the study and further research should be conducted to determine if interventions to alter any of the associated factors will result in improved HRQL, hip function, and health utility for these patients. Additionally, our study included 627 patients, 59% of the those in the FAITH trial. The lower number of patients is because the FAITH trial collected HRQL, hip function, and health utility data from a subset of patients. The collection of these data ceased after the estimated sample size required for secondary HRQL comparisons between the treatment groups were met. Furthermore, our analysis excluded patients who did not have complete data for all factors and respective baseline HRQL, hip function, and health utility measures. Despite this, the study is one of the largest to investigate variables associated with HRQL, hip function, and health utility in patients with a fracture of the femoral neck.

In conclusion, we identified several baseline factors that are associated with lower postfracture HRQL, hip function, and health utility (older age; higher BMI; female gender; ASA class II, III, and IV (compared with class I); a displaced fracture; closed reduction (compared with no reduction); and cancellous screw fixation in current smokers. Aside from a displaced fracture,



closed reduction (compared with no reduction) and cancellous screw fixation in current smokers, we did not find any fracture or surgical characteristics that were associated with lower HRQL scores. These findings may be used to provide patients with more information about their injury and expected outcomes at two years, as well as possibly to guide care.

### Supplemental material

A full list of the FAITH Investigators is available alongside the online version of this article at [www.bjj.boneandjoint.org.uk](http://www.bjj.boneandjoint.org.uk)

### References

1. Thorngren KG. National Registration of Hip Fractures in Sweden. In Bentley G, ed. *European Instructional Lectures*. Vol. 9. Berlin, Heidelberg: Springer, 2009:11–18.
2. Florschutz AV, Langford JR, Haidukewych GJ, Koval KJ. Femoral neck fractures: current management. *J Orthop Trauma* 2015;29:121–129.
3. Parker MJ, Gurusamy K. Internal fixation versus arthroplasty for intracapsular proximal femoral fractures in adults. *Cochrane Database Syst Rev* 2006;4:CD001708.
4. Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) Investigators. Fracture fixation in the operative management of hip fractures (FAITH): an international, multicentre, randomised controlled trial. *Lancet* 2017;389:1519–1527.
5. Papakostidis C, Panagiotopoulos A, Piccioli A, Giannoudis PV. Timing of internal fixation of femoral neck fractures. A systematic review and meta-analysis of the final outcome. *Injury* 2015;46:459–466.
6. Parker MJ, Stockton G. Internal fixation implants for intracapsular proximal femoral fractures in adults. *Cochrane Database Syst Rev* 2001;4:CD001467.
7. Parker MJ, Raghavan R, Gurusamy K. Incidence of fracture-healing complications after femoral neck fractures. *Clin Orthop Relat Res* 2007;458:175–179.
8. Gjertsen JE, Baste V, Fevang JM, Furnes O, Engesaeter LB. Quality of life following hip fractures: results from the Norwegian hip fracture register. *BMC Musculoskelet Disord* 2016;17:265.
9. Peeters CM, Visser E, Van de Ree CL, et al. Quality of life after hip fracture in the elderly: A systematic literature review. *Injury* 2016;47:1369–1382.
10. Campenfeldt P, Hedström M, Ekström W, Al-Ani AN. Good functional outcome but not regained health related quality of life in the majority of 20-69 years old patients with femoral neck fracture treated with internal fixation: A prospective 2-year follow-up study of 182 patients. *Injury* 2017;pii:S0020-1383(17)30716-7. (Epub ahead of print):.
11. Karni S, Bentur N, Ratzon N. Participation and quality of life of cognitively impaired older women in Israel following hip fractures. *Occup Ther Int* 2014;21:91–97.
12. Shyu YI, Chen ML, Chen MC, Wu CC, Su JY. Postoperative pain and its impact on quality of life for hip-fractured older people over 12 months after hospital discharge. *J Clin Nurs* 2009;18:755–764.
13. Tidermark J, Zethraeus N, Svensson O, Törnkvist H, Ponzer S. Femoral neck fractures in the elderly: functional outcome and quality of life according to EuroQol. *Qual Life Res* 2002;11:473–481.

14. Tidermark J, Zethraeus N, Svensson O, Törnkvist H, Ponzer S. Quality of life related to fracture displacement among elderly patients with femoral neck fractures treated with internal fixation. *J Orthop Trauma* 2002;16:34–38.
15. Brooks R. Introduction. In: Brooks R, Rabin R, de Charro F, eds. *The measurement and valuation of health status using EQ-5D: A European perspective*. Dordrecht, Netherlands: Kluwer Academic Publishers, 2003:1-6.
16. FAITH Investigators. Fixation using alternative implants for the treatment of hip fractures (FAITH): design and rationale for a multi-centre randomized trial comparing sliding hip screws and cancellous screws on revision surgery rates and quality of life in the treatment of femoral neck fractures. *BMC Musculoskelet Disord* 2014;15:219.
17. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220–233.
18. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833–1840.
19. Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. *Arthritis Rheum* 2001;45:384–391.
20. Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Qual Life Res* 2005;14:1523–1532.
21. Saklad M. Grading of patients for surgical procedures. *Anesthesiol* 1941;2:281–284.
22. Peduzzi P, Concato J, Kemper E, Holford TR, Feinstein AR. A simulation study of the number of events per variable in logistic regression analysis. *J Clin Epidemiol* 1996;49:1373–1379.
23. Pauwels F. *Der Schenkelhalsbruch, ein mechanisches problem*. Stuttgart: F. Enke, 1935.
24. Bartoníček J. Pauwels' classification of femoral neck fractures: correct interpretation of the original. *J Orthop Trauma* 2001;15:358–360.
25. Mendonça TM, Silva CH, Canto RS, et al. Evaluation of the health-related quality of life in elderly patients according to the type of hip fracture: femoral neck or trochanteric. *Clinics (Sao Paulo)* 2008;63:607–612.
26. Dripps RD. New classification of physical status. *Anesthesiol* 1963;24:111.
27. Deshpande PR, Rajan S, Sudeepthi BL, Abdul Nazir CP. Patient-reported outcomes: A new era in clinical research. *Perspect Clin Res* 2011;2:137–144.
28. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. *J Orthop Surg Res* 2015;10:24.

**Table I.** The characteristics of the 627 patients in the health-related quality of life cohort

<b>Characteristic</b>	<b>Incidence of factors, n (%)</b>
<b>Baseline characteristics</b>	
Mean age, yrs (range)	72.5 (62.4 to 99.0)
<b>Gender</b>	
Female	397 (63.3)
Male	230 (36.7)
Mean BMI, kg/m <sup>2</sup> (range)	24.7 (14.6 to 50.71)
<b>ASA classification</b>	
Class I	108 (17.2)
Class II	309 (49.3)
Class III	188 (30.0)
Class IV	22 (3.5)
Class V	0 (0)
<b>Prefracture living setting</b>	
Institutionalized	15 (2.4)
Not institutionalized	612 (97.6)
<b>Prefracture functional status</b>	
Walking aid	121 (19.3)
Independent ambulator	506 (80.7)
<b>Current Smoker</b>	
Yes	112 (17.9)
No	515 (82.1)
<b>Diabetes</b>	
Yes	98 (15.6)
No	529 (84.4)
<b>Fracture characteristics</b>	
<b>Fracture displacement</b>	
Undisplaced	447 (71.3)
Displaced	180 (28.7)
<b>Level of the fracture line</b>	
Subcapital	415 (66.2)
Midcervical	185 (29.5)
Basal	27 (4.3)
<b>Pauwels classification</b>	
Type I	65 (10.4)
Type II	472 (75.3)
Type III	90 (14.4)
<b>Surgical characteristics</b>	
<b>Type of reduction</b>	
None	209 (33.3)
Closed	386 (61.6)
Open	32 (5.1)
<b>Quality of implant placement</b>	
Acceptable	594 (94.7)
Unacceptable	33 (5.3)
<b>Randomized treatment group</b>	
Cancellous screws	299 (47.7)
Sliding hip screw	328 (52.3)
Mean time from injury to surgery, hrs (range)	49.0 (2.95 to 693.83)

BMI, body mass index; ASA, American Society of Anesthesiologists

**Table II.** Results from primary multilevel mixed model regression with the 12-item Short Form Health Survey Physical Component Score (SF-12 PCS) as the dependent variable for 563 patients, adjusted for baseline SF-12 PCS

<b>Independent variable</b>	<b>Adjusted mean difference (95% CI)</b>	<b>p-value*</b>
<b>Baseline patient characteristics</b>		
Age, yrs (10-yr increase)	-1.42 (-2.17 to -0.67)	< 0.001
Female gender	-1.52 (-3.00 to -0.05)	0.04
BMI, kg/m <sup>2</sup> (5-point increase)	-0.69 (-1.36 to -0.02)	0.04
<b>ASA classification</b>		
Class II vs class I	-1.29 (-3.31 to 0.74)	0.21
Class III vs class I	-3.19 (-5.73 to -0.66)	0.01
Class IV vs class I	-3.39 (-7.86 to 1.07)	0.17
Independent ambulator	0.21 (-1.89 to 2.31)	0.85
Institutionalized	-0.74 (-6.55 to 5.06)	0.80
Diabetic	-0.47 (-2.39 to 1.45)	0.63
<b>Fracture characteristics</b>		
Displaced fracture	-2.18 (-3.88 to -0.49)	0.01
<b>Level of the fracture line</b>		
Midcervical vs basal	2.98 (-0.51 to 6.48)	0.09
Subcapital vs basal	1.34 (-1.98 to 4.66)	0.43
<b>Pauwels classification</b>		
Type I vs type III	-2.50 (-5.65 to 0.65)	0.12
Type II vs type III	-2.14 (-4.41 to 0.12)	0.63
<b>Surgical characteristics</b>		
<b>Type of reduction</b>		
Open vs none	1.43 (-1.79 to 4.66)	0.38
Closed vs none	-1.11 (-2.76 to 0.53)	0.19
Unacceptable quality for implant placement	-1.06 (-4.07 to 1.95)	0.49
Time from injury to surgery	0.03 (-2.26 to 2.33)	0.98
<b>Interaction term</b>		
<b>Current smokers</b>		
Sliding hip screw vs cancellous screws	3.35 (0.03 to 6.67)	0.048
<b>Former/non-smokers</b>		
Sliding hip screw vs cancellous screws	-0.37 (-1.81 to 1.07)	0.61
<b>Sliding hip screw</b>		
Current smokers vs former/non-smokers	0.04 (-2.46 to 2.53)	0.98
<b>Cancellous screws</b>		
Current smokers vs former/non-smokers	-3.69 (-6.48 to -0.89)	0.01

\*p-values were obtained from the tests of significance for the beta coefficients in the multilevel mixed model regression analysis  
CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists

**Table III.** Results from multilevel mixed model regression with the 12-item Short Form Health Survey Mental Component Score (SF-12 MCS) as the dependent variable for 563 patients, adjusted for baseline SF-12 MCS

<b>Independent variable</b>	<b>Adjusted mean difference (95% CI)</b>	<b>p-value*</b>
<b>Baseline patient characteristics</b>		
Age, yrs (10-yr increase)	-0.01 (-0.73 to 0.71)	0.97
Female gender	-2.10 (-3.50 to -0.71)	0.003
BMI, kg/m <sup>2</sup> (5-point increase)	-0.41 (-1.04 to 0.23)	0.21
<b>ASA classification</b>		
Class II vs class I	-1.34 (-3.21 to 0.52)	0.16
Class III vs class I	-3.17 (-5.49 to -0.84)	0.01
Class IV vs class I	-2.44 (-6.75 to 1.87)	0.27
Independent ambulator	1.27 (-0.65 to 3.19)	0.20
Institutionalized	4.98 (-0.54 to 10.49)	0.08
Diabetic	-1.02 (-2.87 to 0.82)	0.28
<b>Fracture characteristics</b>		
Displaced fracture	-1.80 (-3.39 to -0.21)	0.02
<b>Level of the fracture line</b>		
Midcervical vs basal	0.10 (-3.20 to 4.40)	0.95
Subcapital vs basal	0.54 (-2.61 to 3.68)	0.74
<b>Pauwels classification</b>		
Type I vs type III	-0.64 (-3.61 to 2.33)	0.67
Type II vs type III	0.54 (-1.58 to 2.67)	0.62
<b>Surgical characteristics</b>		
<b>Type of reduction</b>		
Open vs none	0.67 (-2.45 to 3.78)	0.67
Closed vs none	0.33 (-1.23 to 1.90)	0.68
Unacceptable quality for implant placement	-1.92 (-4.74 to 0.89)	0.18
Time from injury to surgery	-1.82 (-3.97 to 0.34)	0.10
<b>Interaction term</b>		
<b>Current smokers</b>		
Sliding hip screw vs cancellous screws	0.78 (-2.34 to 3.91)	0.62
<b>Former/non-smokers</b>		
Sliding hip screw vs cancellous screws	0.02 (-1.34 to 1.39)	0.97
<b>Sliding hip screw</b>		
Current smokers vs former/non-smokers	-1.41 (-3.74 to 0.93)	0.24
<b>Cancellous screws</b>		
Current smokers vs former/non-smokers	-2.17 (-4.79 to 0.46)	0.11

\*p-values were obtained from the tests of significance for the beta coefficients in the multilevel mixed model regression analysis

CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists

**Table IV.** Results from multilevel mixed model regression with Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score as the dependent variable for 604 patients, adjusted for baseline WOMAC score

<b>Independent variable</b>	<b>Adjusted mean difference (95% CI)</b>	<b>p-value*</b>
<b>Baseline patient characteristics</b>		
Age, yrs (10-yr increase)	0.22 (-1.12 to 1.56)	0.74
Female gender	1.36 (-1.31 to 4.04)	0.32
BMI, kg/m <sup>2</sup> (5-point increase)	1.16 (-0.07 to 2.39)	0.06
<b>ASA classification</b>		
Class II vs class I	1.51 (-2.05 to 5.07)	0.41
Class III vs class I	3.64 (-0.74 to 8.03)	0.10
Class IV vs class I	5.92 (-2.46 to 14.30)	0.17
Independent ambulator	-2.75 (-6.48 to 0.97)	0.15
Institutionalized	-1.73 (-11.02 to 7.55)	0.71
Diabetic	1.66 (-1.82 to 5.14)	0.35
<b>Fracture characteristics</b>		
Displaced fracture	3.77 (0.73 to 6.81)	0.02
<b>Level of the fracture line</b>		
Midcervical vs basal	-3.42 (-9.78 to 2.94)	0.29
Subcapital vs basal	-0.49 (-6.54 to 5.56)	0.87
<b>Pauwels classification</b>		
Type I vs type III	4.29 (-1.34 to 9.92)	0.14
Type II vs type III	2.73 (-1.33 to 6.79)	0.19
<b>Surgical characteristics</b>		
<b>Type of reduction</b>		
Open vs none	-0.28 (-6.48 to 5.92)	0.93
Closed vs none	1.60 (-1.31 to 4.52)	0.28
Unacceptable quality for implant placement	1.68 (-3.69 to 7.05)	0.54
Time from injury to surgery	2.44 (-1.69 to 6.58)	0.25
<b>Interaction term</b>		
<b>Current smokers</b>		
Sliding hip screw vs cancellous screws	-4.71 (-10.61 to 1.19)	0.12
<b>Former/non-smokers</b>		
Sliding hip screw vs cancellous screws	1.53 (-1.07 to 4.14)	0.25
<b>Sliding hip screw</b>		
Current smokers vs former/non-smokers	0.10 (-4.39 to 4.58)	0.97
<b>Cancellous screws</b>		
Current smokers vs former/non-smokers	6.34 (1.42 to 11.26)	0.01

\*p-values were obtained from the tests of significance for the beta coefficients in the multilevel mixed model regression analysis

CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists

**Table V.** Results from multilevel mixed model regression with EuroQol (EQ)-5D score as the dependent variable for 581 patients, adjusted for baseline EQ-5D score

<b>Independent variable</b>	<b>Adjusted mean difference (95% CI)</b>	<b>p-value*</b>
<b>Baseline patient characteristics</b>		
Age, yrs (10-yr increase)	-0.01 (-0.02 to -0.002)	0.02
Female gender	-0.04 (-0.06 to -0.02)	< 0.001
BMI, kg/m <sup>2</sup> (5-point increase)	-0.02 (-0.03 to -0.01)	< 0.001
<b>ASA classification</b>		
Class II vs class I	-0.03 (-0.05 to -0.001)	0.04
Class III vs class I	-0.07 (-0.11 to -0.04)	< 0.001
Class IV vs class I	-0.10 (-0.17 to -0.04)	0.002
Independent ambulator	0.02 (-0.01 to 0.05)	0.14
Institutionalized	0.03 (-0.04 to 0.11)	0.43
Diabetic	-0.02 (-0.05 to 0.004)	0.09
<b>Fracture characteristics</b>		
Displaced fracture	-0.05 (-0.07 to -0.03)	< 0.001
<b>Level of the fracture line</b>		
Midcervical vs basal	-0.01 (-0.06 to 0.04)	0.70
Subcapital vs basal	-0.02 (-0.07 to 0.02)	0.33
<b>Pauwels classification</b>		
Type I vs type III	-0.04 (-0.08 to 0.01)	0.09
Type II vs type III	-0.01 (-0.04 to 0.02)	0.43
<b>Surgical characteristics</b>		
<b>Type of reduction</b>		
Open vs none	0.01 (-0.04 to 0.05)	0.82
Closed vs none	-0.03 (-0.05 to -0.01)	0.01
Unacceptable quality for implant placement	-0.02 (-0.06 to 0.02)	0.37
Time from injury to surgery	-0.005 (-0.02 to 0.04)	0.65
<b>Interaction term</b>		
<b>Current smokers</b>		
Sliding hip screw vs cancellous screws	0.03 (-0.01 to 0.07)	0.17
<b>Former/non-smokers</b>		
Sliding hip screw vs cancellous screws	-0.005 (-0.02 to 0.01)	0.62
<b>Sliding hip screw</b>		
Current smokers vs former/non-smokers	-0.01 (-0.04 to 0.02)	0.59
<b>Cancellous screws</b>		
Current smokers vs former/non-smokers	-0.04 (-0.08 to -0.01)	0.02

\*p-values were obtained from the tests of significance for the beta coefficients in the multilevel mixed model regression analysis

CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists